K121309

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8. 510(K) SUMMARY

8.1 SUBMITTER/510(K) HOLDER

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SEP 6 2012

8.2 CONSULTANT

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8.3 ESTABLISHMENT REGISTRATION NUMBER:

9616720

8.4 DATE PREPARED:

April 30, 2012

8.5 DEVICE NAME & CLASSIFICATION

Proprietary Name:	ASC QuadPort+ Laparoscopic Access Devices
Common/Usual Name:	Laparoscopic Single Port Access Device
Classification Name:	Endoscope and Accessories (21 CFR §876.1500)
Classification Number:	Class II
Product Code:	OTJ

8.6 PREDICATE DEVICE

ASC TriPort+ Laparoscopic Access Device (K110004)

8.7 DEVICE DESCRIPTION

The ASC QuadPort+ Laparoscopic Access Devices are, like the parent TriPort+ device cleared by the FDA under K110004, laparoscopic multi-instrument ports which perform the following two functions.

- Retracting a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen at the same time during laparoscopic surgery.
- Ensuring that pneumoperitoneum is maintained in the abdomen during the surgical procedure, whether or not one or more laparoscopic instruments are passing through the device.

The QuadPort+ laparoscopic multi-instrument port is sterile and disposable. The QuadPort+ laparoscopic multi-instrument ports perform the same function as the TriPort+ parent device.

Like the parent ASC TriPort+ Laparoscopic Access Device, the QuadPort+ laparoscopic multi-instrument port is comprised of the following three components:

- An *introducer component*, which delivers the Distal Ring of the device through a pre-made incision, into the abdominal cavity.
- A *retractor component*, which retracts an abdominal incision to allow the passage of laparoscopic instruments.
- A *valve component* which maintains the pneumoperitoneum established for the surgical procedure.

The QuadPort+ laparoscopic multi-instrument port is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery. The QuadPort+ laparoscopic multi-instrument port functions in the same way as the ASC parent TriPort+ device cleared by the FDA under K110004.

QuadPort+ Modifications

The modifications to the TriPort + (K110004) to produce the QuadPort+ are as follows:

- A change in the configuration of the valve sizes
- The addition of an extra port to allow greater flexibility regarding instrument placement
- Range of Valve sizes is larger (QuadPort+ can accommodate 12 and 15mm instruments)
- Device is larger, to allow use through larger incision (25-60mm)
- Valve housing section (boot) is overmolded to ensure it remains in position
- Packaging redesign.

The changes made to the parent Triport + Laparoscopic Access Device to produce the QuadPort+ are minor and do not represent change to its intended use, fundamental scientific technology, operating principles or mechanism of actuation of the device.

8.8 INTENDED USE

The QuadPort+ laparoscopic multi-instrument port is intended for use as multiple instrument and/or camera port during minimally-invasive abdominal laparoscopic surgery.

8.9 TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The QuadPort+ Laparoscopic Access Device provides an access path for multiple laparoscopic instruments through a small incision in the abdominal wall. Its function is the same as that of the parent TriPort + Laparoscopic Access Device (K110004).

The QuadPort+ and the parent TriPort+ Laparoscopic Access devices are Laparoscopic instrument ports. As with the TriPort +, the QuadPort+ retracts an abdominal incision to allow laparoscopic instruments to pass through into the abdomen, and maintains pneumoperitoneum in the abdomen during the surgical procedure, whether or not laparoscopic instruments are passing through the port.

Both the Quadport+ and the predicate TriPort + allow the option for the simultaneous introduction of up to four laparoscopic instruments through a single incision.

Like the predicate device, the QuadPort+ device is a sterile, single use (disposable) device.

The insertion method for the QuadPort+ is the same as that for the TriPort +. This introducer is identical in actuation to that already supplied with the approved TriPort+(K110004). The distal ring is inserted, using this introducer, into the abdominal cavity through a pre-made incision.

8.10 PERFORMANCE TESTING

Design Verification testing of the QuadPort+ demonstrates that the modifications that are the subject of this notification do not raise new issues of safety or effectiveness. Validation activities included repeating all those tests carried out on the parent device as well as any others highlighted as part of Risk Analysis. Validation testing of the QuadPort+ in a porcine model enrolled clinicians who were experienced with single port devices to demonstrate the device functioned as intended when used in a variety of laparoscopic procedures, that the performance did not raise any new issues of safety and effectiveness, and that the IFU adequately allowed for the use of the device without any further training.

The device functioned as expected and showed the following:

a. The device was easy to insert,
b. Instruments are easy to insert and withdraw,
c. Device maintained pneumoperitoneum
d. Surgeons were able to manipulate instruments for a laparoscopic procedure
e. Surgeons were able to conduct a typical laparoscopic procedure
f. The device stayed in position during surgery.

8.11 CONCLUSIONS

Following Design Verification testing of the QuadPort+ along with Design Validation testing in a porcine model and on a simulator, the device has met the defined design and performance requirements outlined in the Design Inputs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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SEP 6 2012

Re: K121309
Trade/Device Name: ASC Quad + Laparoscopic Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ
Dated: August 10, 2012
Received: August 10, 2012

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121309

Device Name: ASC QuadPort+ Laparoscopic Access Device

Indications For Use:

The QuadPort+ is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.

Prescription Use: X AND/OR Over-The-Counter Use:

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121309